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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/568,226	02/14/2006	Yasuo Kunugiza	GRT/423-72	6159

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EXAMINER	
EPPS FORD, JANET L	
ART UNIT	PAPER NUMBER
1633	

MAIL DATE	DELIVERY MODE
07/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/568,226	KUNUGIZA ET AL.	
	Examiner	Art Unit	
	Janet L. Epps-Ford	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11-18 and 20* is/are rejected.

7)☒ Claim(s) *10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *2-16-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group 1 (claims 1-18), drawn to a staple oligonucleotide of formula SEQ ID NO: 1, in the reply filed on 4-17-2008 is acknowledged. The traversal is on the ground(s) that the examination of Groups I to III would not constitute a serious burden. This is not found persuasive because although SEQ ID NOS: 1-3 share some structural similarities, nevertheless overall each claimed staple oligonucleotide comprise a different nucleotide sequence and therefore require a separate search and consideration of the prior art.

The requirement is still deemed proper and is therefore made FINAL.

2. Groups II-III, drawn to SEQ ID NO: 2-3 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 4-17-2008.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-, 6, 8-9, and 11-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Vasseur et al. (WO 94/23026).

5. Claim 1 recites the following:

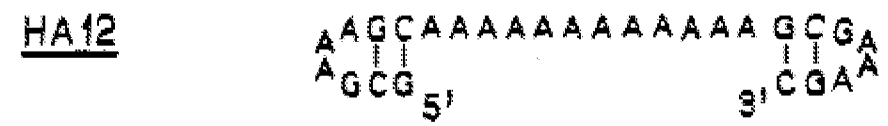
1. (original) A staple oligonucleotide which is a single-stranded oligonucleotide comprising a 5'-end sequence, an intermediate sequence and a 3'-end sequence, the 5'-end sequence having a reverse complementarity with the intermediate sequence, the 3'-end sequence having a reverse complementarity with the intermediate sequence and the intermediate sequence having loops at both ends, the loops each comprising three to ten nucleotides and not forming a complementary bond intermolecularly.

6. (previously presented) The staple oligonucleotide according to claim 1, wherein the loops each comprise 4 to 6 nucleotides in length.

8. (previously presented) The staple oligonucleotide according to claim 1, wherein the oligonucleotide is a DNA or a DNA derivative.

9. (previously presented) The staple oligonucleotide according to claim 1, whose phosphate groups are not phosphorothioated.

The following structure is disclosed in Vasseur et al. in Figures 2A and 4a. This structure meets all the limitations recited in instant claims 1, 6, and 8-9, particularly wherein the staple oligonucleotide comprises a 3'-end and a 5'end comprising reverse complementarity, and 4-nucleotide loops on both ends. The disclosed oligonucleotide is a DNA derivative, and there is no indication that the compounds are phosphorothioated, see Figure 1.

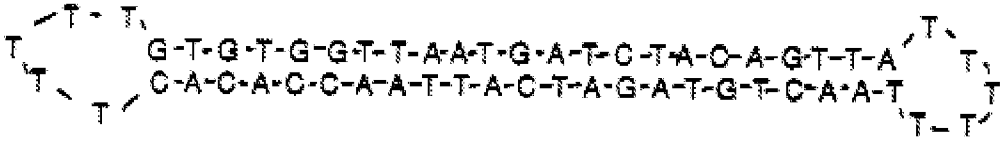


In regards to the intended use limitations recited in instant claims 11-18, particularly wherein the generically claimed staple oligonucleotide is disclosed as a "medicament," absent evidence to the contrary, since the prior art describes the general structure recited in instant claim 1, the prior art structure would have to also meet the intended use limitations recited in the instant claims, and thus anticipate the claimed invention.

6. Claims 1-9, 11-18 are rejected under 35 U.S.C. 102 (b) as being anticipated by Blumenfeld et al. (WO 9219731 A1).

Figure 5B of this reference discloses the following:

FIGURE 5-B.



This compound comprises 48 nucleotides in length, and thus falls within the range of 42 to 54 nucleotides as recited in the instant claims, and further comprises loops of 4 to 6 nucleotides in length.

In regards to the intended use limitations recited in instant claims 11-18, particularly wherein the generically claimed staple oligonucleotide is disclosed as a "medicament," absent evidence to the contrary, since the prior art describes the general structure recited in instant claim 1, the prior art structure would have to also meet the intended use limitations recited in the instant claims, and thus anticipate the claimed invention.

7. Claims 1-9, 11-18 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Ahn et al.

8. Ahn et al. describe decoy oligonucleotides which specifically bind the transcription factor E2F, see Figure 1, CDODN, MODN is the mutated control.

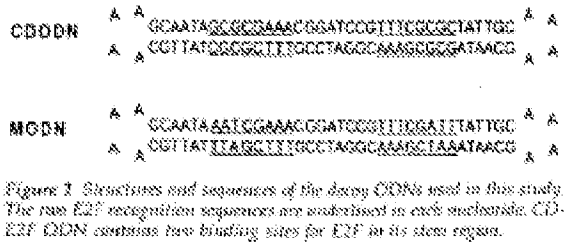


Figure 1. Structures and sequences of the decoy ODNs used in this study. The core E2F recognition sequences are underlined in each nucleotide. CD-E2F ODN contains two binding sites for E2F in its stem region.

9.

10. Ahn et al. demonstrated that the E2F decoy, CD-ODN inhibited the growth of vascular smooth muscle cells in vitro, and further demonstrated a significant reduction of neointimal formation in a dose dependent manner comprising the administration of CD-ODN in vivo.

Allowable Subject Matter

11. Claim 10 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten to recite the elected subject matter, and further rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Ford/
Primary Examiner, Art Unit 1633

/J. L. E./
Primary Examiner, Art Unit 1633